

IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10918/004/001**

Case No: 7008222

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Evans Vanodine International Plc

Brierley Road, Walton Summit, Preston PR5 8AH

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Masodip Platinum 0.436 % w/v Teat Dip/Spray Solution

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation, unless revoked, shall continue in force from **25/08/2010**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Masodip Platinum 0.436 % w/v Teat Dip/Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Chlorhexidine gluconate 0.436 % w/v
(as Chlorhexidine digluconate solution)

Excipients

Benzalkonium chloride 0.01 % w/v
Ponceau 4R (E 124) 0.0021 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat dip/Spray Solution
A clear red liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cattle.

4.2 Indications for use, specifying the target species

As an aid in the control of mastitis in lactating dairy cows and in the prevention and healing of chapped teats.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

Wash udders and teats before next milking.

If signs of disease persist or appear, consult your veterinary surgeon or veterinary practitioner.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with eyes. If splashed in the eyes, rinse with clean running water and seek medical advice.

In case of ingestion, seek medical attention immediately.

When used as a spray, avoid working in a spray mist.

Do not eat, drink or smoke whilst using the product.

Keep away from animal feed.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For topical administration to the teats.

Applied undiluted for dipping or spraying cows' teats immediately after milking.

Teat Dipping

No dilution is required. Fill teat dipping cup about two thirds with Masodip Platinum 0.436 % w/v Teat Dip/Spray Solution. Dip teats of every cow immediately after each cow is milked, ensuring that the full length of each teat is covered. Top up the cup with fresh solution as required. Teat dip cups should be emptied and washed after milking.

Teat Spraying

No dilution is required. Immediately after milking spray the entire surface of each teat of every cow with Masodip Platinum 0.436 % w/v Teat Dip/Spray Solution.

Udder Washing and Cluster Dipping

Dilute in the proportion 1 part Masodip Platinum 0.436 % w/v Teat Dip/Spray Solution to 67 parts water (i.e. 2.4 fl.oz. per gallon or 150 ml per 10 litres).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: 0 days.

Milk: 0 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, antiseptics and disinfectants, biguanides and amidines, chlorhexidine.

ATC vet code: QD08AC02

Active ingredient:

Chlorhexidine is a bisbiguanide antiseptic and disinfectant which is bactericidal or bacteriostatic against a wide range of Gram positive and Gram negative bacteria.

It is more effective against Gram positive than Gram negative bacteria, some species of *Pseudomonas* and *Proteus* being less susceptible. It inhibits mycobacteria. Chlorhexidine inhibits some viruses and is active against some fungi. It is inactive against bacterial spores at room temperature.

For pre-operative skin disinfection and hand washing, chlorhexidine is used as a 0.5% solution of the acetate or gluconate in alcohol (70%) or as in a 4% detergent solution of the gluconate.

For disinfection of wounds, burns, or other skin damage disorders, chlorhexidine is used as a 0.05% aqueous solution of the gluconate.

For the emergency disinfection of clean instruments a 2 minute immersion in chlorhexidine acetate or gluconate 0.5% in alcohol (70%) is used.

In obstetrics, chlorhexidine gluconate is used as a 0.05% aqueous solution or a 1% cream. The cream is also used as a barrier against bacterial hand infection.

5.2 Pharmacokinetic properties

Active ingredient:

Chlorhexidine is poorly absorbed from the gastro-intestinal tract and skin.

Chlorhexidine was detected in low concentrations in the venous blood of 5 of 24 infants after bathing with a preparation containing chlorhexidine gluconate 4%. No adverse effects due to percutaneous absorption of chlorhexidine were observed. Low concentrations have been found in the venous blood of neonates following the topical use of a powder containing chlorhexidine 1%.

Percutaneous absorption of chlorhexidine was reported in pre-term neonates (but not full term infants) treated with chlorhexidine 1% in alcohol for neonatal cord care; no such absorption occurred when a dusting powder containing chlorhexidine 1% and zinc oxide 3% was used.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol (non-crystallising)
Isopropyl Alcohol
C₁₃C₁₅Alcohol Ethoxylate
Benzalkonium Chloride
Ponceau 4R (E124)
Deionised water

6.2 Incompatibilities

Chlorhexidine gluconate is incompatible with soaps and other anionic materials and with suspending agents such as alginates and tragacanth. At concentrations of 0.05% chlorhexidine salts are incompatible with borates, bicarbonates, carbonates, chlorides, citrates, nitrates, phosphates and sulphates, forming salts of low solubility. Precipitates may form in hard water. Chlorhexidine is inactivated by cork.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Store in tightly closed original container. Store below 25°C.
Protect from frost.

6.5 Nature and composition of immediate packaging

High density polyethylene 25 litre and 200 litre drums fitted with tamper-evident polypropylene cap.
High density polyethylene 5 litre drum with wadded polypropylene cap (screw fit).

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers.

7 MARKETING AUTHORISATION HOLDER

Evans Vanodine International PLC,
Brierley Road,
Walton Summit,
Preston, PR5 8AH,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10918/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

25th August 2010